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ORIGINAL REPORT

COUGH ASSISTANCE DEVICE FOR PATIENTS WITH GLOTTIS DYSFUNCTION AND/OR TRACHEOSTOMY

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Objective: **To estimate the efficiency of a cough assistance device, the Cough Aid, in patients with weak respiratory muscles with bulbar palsy and/or tracheostomy. The Cough Aid is a device that has been developed to substitute for glottis function.**

Design: **Before-after trial.**

Subjects/patients: **A total of 74 patients with bulbar palsy and/or tracheostomy, as well as respiratory muscle weakness, were recruited.**

Methods: **Forced vital capacity, unassisted cough peak flow, lung insufflation capacity, and assisted cough peak flow were measured via tracheostomy or oronasal interface. Lung insufflation capacity and assisted cough peak flow were measured using the Cough Aid.**

Results and conclusion: **In all 74 subjects, lung insufflation capacities measured with the device were significantly higher than forced vital capacities ($p<0.01$). Assisted cough peak flows measured using the device were also significantly higher than unassisted cough peak flows ($p<0.01$). The Cough Aid is effective in helping to increase cough flow and assisting in the air stacking exercise by substituting the function of the glottis in patients who have glottis dysfunction or a tracheostomy tube.**

Key words: cough; glottis; bulbar palsy; tracheostomy; cough aid.

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INTRODUCTION

An effective cough is an indispensable host defence mechanism for clearing the airways (1). Ineffective coughing leads to pulmonary complications, such as pneumonia and atelectasis (2, 3). The phases of cough are classified as: (*i*) inspiratory, (*ii*) compressive, and (*iii*) expiratory (1, 4, 5). The inhalation of a large volume of air characterizes the inspiratory phase. In the compressive phase the glottis is closed and intra-thoracic pressure is increased. In the expiratory phase the glottis is opened and the expiratory muscles contract. A cough is ineffective when only one of these phases fails.

A manually assisted cough helped by abdominal thrust improves cough flow dynamics and can help patients whose expiratory muscles are weak (6, 7). For patients who have weak inspiratory muscles, receiving maximal insufflations via a manual resuscitation bag or by air-stacking before a manual thrust can create an effective cough (8, 9).

When glottis closure is incomplete or tracheostomized in patients with expiratory muscle weakness, an increase in the intra-thoracic pressure will be ineffective. Thus, the efficient expiratory flows required for coughing cannot be obtained. For some patients who have sufficient expiratory muscle strength and can generate huffing, glottis closure appears not to be critical for the development of an effective cough. However, glottis closure is an important contributory factor, and it is difficult to augment a cough by assisted coughing methods in patients with weakened expiratory muscle activation and impaired glottis function (10–12). Therefore, a device that supports impaired bulbar muscle function will help many patients who cannot cough due to bulbar muscle weakness or tracheostomy. External glottis closure is needed to induce maximum passive lung insufflation in patients with glottis dysfunction and/or tracheostomy. Passive lung insufflation can be achieved by using a manual resuscitator connected to a spirometer, with the expiratory port of the spirometer occluded during insufflation. Using this method sufficient lung insufflation capacity (LIC) can be obtained (13).

We have previously developed and tested such a device as a prototype and have shown the effectiveness of external control of exhalation in patients with glottis dysfunction and/or tracheostomy (14).

A new model for external control of exhalation has now been developed that is simpler and easier to use in the clinical situation. The aim of this study is to evaluate how the new device affects cough augmentation in patients with glottis dysfunction and/or tracheostomy.

METHODS

"Cough Aid" design

The Cough Aid comprises two parts: the connection part and the control part, as follows.

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The connection part is a T-shape plastic tube with 3 main air pathways: a patient connection port, an insufflation port, and an exsufflation port (Fig. 1A). The patient connection port is connected to the patients' airway via an oronasal mask or tracheostomy tube. A manual resuscitation bag can be connected to the cylindrical-shaped insufflation port located in the centre at a right angle to the device, and the airstream from the resuscitation bag passes through a one-way valve, which cannot leak (Fig. 1B). The exsufflation port is the air pathway connected to the control part. The control part, the essential part of the Cough Aid, enables the patient artificially to modulate the function of glottic opening and closing (Fig. 1A). When the pushing bar is not pressed, it blocks the exhaust holes, so that the air cannot pass through the control part. When the pushing bar is pressed, the airflow can pass through the control part via opened exhaust holes, which are the only route by which air can exit from the device.

When the pushing bar is not pressed, additional air can be instilled to the patient's lungs by using a manual resuscitation bag just after the patient's voluntary maximal inhalation. The Cough Aid was designed to allow no leakage of insufflated air and to hold enough air to increase the intra-thoracic pressure sufficiently for a cough-like exhalation (Fig. 1C). When the pushing bar is pressed the control part acts exactly like the glottis; exhaled air passes freely from the connection part to the outside of the device through the exhaust holes of the control part. Thus, patients are able to exhale with a fast airflow, similar to normal cough augmentation with an intact glottis function.

This trial was approved by the Institutional Review Board of the Kangnam Severance Hospital, Yonsei University College of Medicine in Seoul, South Korea (3-2008-0119).

Patients

A total of 74 patients with bulbar palsy and/or tracheostomy, as well as inspiratory and expiratory muscle weakness, were recruited in this study. The patients, who had dysarthria and/or dysphagia, were considered to have bulbar dysfunction, and they could not hold inhaled air to measure cough peak flow (CPF) after air stacking with a resuscitation bag in the preliminary study. Exclusion criteria were: lung disease, or inability to co-operate due to mental or physical problems. The study was approved by the institutional review board, and informed consent was obtained from all study subjects.

Clinical evaluation

Forced vital capacity (FVC) and lung insufflation capacity (LIC). The FVC and LIC were measured to evaluate briefly the pulmonary function status of the patients. The FVC was measured in the sitting position using a commercial flow analyser test system (Certifier® FA, TSI Inc., Shoreview, MN, USA) via a tracheostomy tube or oronasal interface. This process was repeated at least 3 times; the highest value being selected as the FVC. The LIC by air stacking was achieved when the patient took a deep breath, held it, and then a maximum volume was delivered through the Cough Aid while the pushing bar was not pressed. The patient then exhaled the maximally held volume of air into a commercial flow analyser test system (Certifier® FA, TSI Inc., Shoreview, MN, USA) through the Cough Aid with the pushing bar pressed. The maximum value of 3 or more attempts was recorded.

Unassisted CPF (UCFP) and assisted CPF (ACPF) using the Cough Aid. The UCPF was measured using a commercial flow analyser test system (Certifier® FA) by having the subject cough as forcefully as possible through the Cough Aid at the same time as the pushing bar was pressed for air to pass through the Cough Aid. To measure the ACPF, maximal air stacking was performed through the Cough Aid while the pushing bar was not pressed. The patient then attempted to cough when the pushing bar was pressed and manual abdominal thrust was applied. For tracheostomized patients, the CPFs under different conditions were measured through a tube with the cuff inflated. The maximum value of 3 or more attempts was recorded.

Data analysis

The paired *t*-test was used to determine whether the difference between the UCPF and ACPF was significant. If two parameters showed statistical significance, it was assumed that the Cough Aid was effective in cough augmentation of the patients with bulbar palsy and/or tracheostomy. Data were analysed using SPSS 15.0. A p-value < 0.05 was considered statistically significant.

RESULTS

A total of 74 subjects who met the criteria were evaluated. Twenty-seven of the subjects had bulbar palsy and were diagnosed as amyotrophic lateral sclerosis (ALS). The parameters were measured via the oronasal interface in this group (Group 1). Forty-seven subjects had tracheostomy tubes, so the parameters had to be evaluated through the tracheostomy tubes. In this group (Group 2), 15 were ALS patients and 24 had cervical spinal cord injuries. The remaining 8 patients had Duchenne muscular dystrophy, Guillain-Barré syndrome, multiple sclerosis, and stroke, etc. (Table I).

In all the 74 subjects, the LICs (mean 1536.9 ml, standard deviation (SD) 714.9 ml) measured by a commercial flow analyser test system (Certifier® FA) using the Cough Aid were significantly higher than FVCs (mean 904.8 ml, SD 536.5 ml, $p < 0.01$). The same patterns were observed in Group 1 and 2 ($p < 0.01$) (Table II).

The ACPFs (mean 133.5 l/min, SD 72.6 l/min) measured using the Cough Aid were significantly higher than the UCPFs

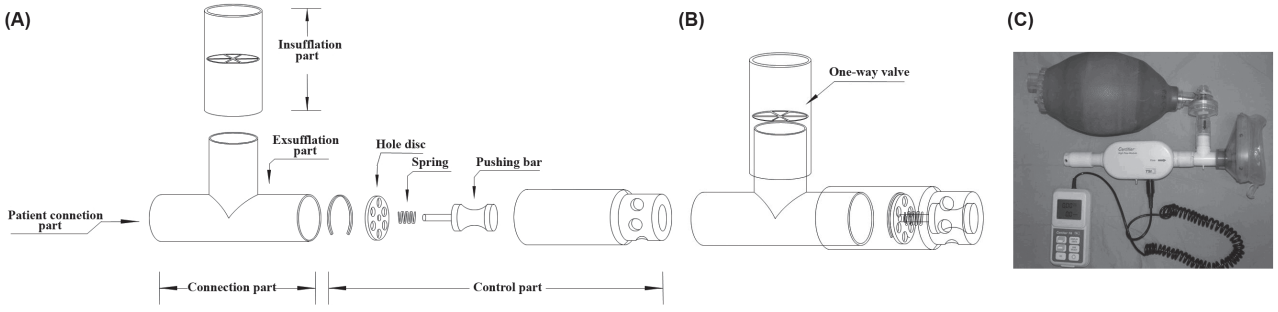

Fig. 1. "Cough Aid" device. When performing air-stacking exercise and cough-assisting method, previously inhaled air does not leak though the valve; when the patient exhales or coughs, the pushing bar is pressed at the same time and the exhaled air is exhausted through the concave portion of the pushing bar. (A) Disassembled view. (B) Complete view showing inner parts. (C) The device connected to a manual resuscitation bag.

Table I. *Subjects' characteristics*

	Total (n=74)	Group 1 (n=27)	Group 2 (n=47)
Sex, *n*			
Men	54	18	36
Women	20	9	11
Age, years, mean (SD)	52.9 (12.5)	56.0 (11.0)	51.1 (13.1)
Height, cm, mean (SD)	166.4 (10.1)	163.6 (12.3)	168.0 (8.4)
Weight, kg, mean (SD)	57.3 (11.8)	57.3 (14.3)	57.3 (10.3)
Diagnosis, *n*			
ALS	42	27	15
Cervical SCI	24		24
DMD	1		1
GBS	1		1
MS	1		1
Stroke	2		2
MG	2		2
SMA type 3	1		1

Group 1: patients with bulbar palsy all diagnosed as ALS without tracheostomy. Group 2: patients with tracheostomy.
ALS: amyotrophic lateral sclerosis; SCI: spinal cord injury; DMD: Duchenne muscular dystrophy; GBS: Guillain-Barré syndrome; MS: multiple sclerosis; MG: myasthenia gravis; SMA: spinal muscular atrophy; SD: standard deviation.

(mean 73.9 l/min, SD 49.7 l/min) in a total of 74 subjects ($p<0.01$). Also, in Groups 1 and 2, the ACPFs were significantly higher than the UCPF ($p<0.01$) (Table II).

DISCUSSION

To produce an effective cough, all phases of cough augmentation are important: inspiration, expiration, and compression. Impaired inspiratory function can be substituted by a manual insufflation bag to supply an additional volume of air (11), and weak expiratory muscles can be assisted by an abdominal thrust (15). The combination of both air stacking and abdominal thrust is better than either alone (9). However, in the case of a patient with a failed glottis and/or a tracheostomy, very few methods can help. The failure of the glottis causes problems in the compressive phase, thus it is impossible to hold the pre-cough volume, and an effective cough flow cannot be established. Even though the air has been supplied, it leaks out from the lungs.

Table II. *Results of pulmonary function test for the subjects*

	Total (n=74) Mean (SD)	Group 1 (n=27) Mean (SD)	Group 2 (n=47) Mean (SD)
FVC, ml	904.8 (536.5)*	1,060.2 (547.0)*	815.5 (515.1)*
LIC, ml	1,536.9 (714.9)*	1,599.5 (907.4)*	1,501.0 (584.8)*
UCPF, l/min	73.9 (49.7)*	104.7 (51.2)**	56.1 (39.5)*
ACPF, l/min	133.5 (72.6)*	174.7 (89.3)**	109.8 (47.8)*

*Paired t-test, $p<0.01$, **Paired t-test, $p=0.01$.
Group 1: patients with bulbar palsy all diagnosed as ALS without tracheostomy. The parameters were evaluated via oronasal interface. Group 2: patients with tracheostomy.
FVC: forced vital capacity; LIC: lung insufflation capacity; UCPF: unassisted cough peak flow; ACPF: assisted cough peak flow; SD: standard deviation.

Tracheostomized patients also cannot produce an effective cough. These patients have difficulty initiating the compressive phase, and cough flow cannot be accrued sufficiently by using the several cough-assisted methods (16, 17). Therefore, passive lung insufflation by LIC could be significantly greater than air stacking in patients with bulbar palsy (13).

We developed the simple Cough Aid device, which provided the benefit of sufficient LIC, and clinically proved its usefulness. This device could be applied to patients with glottis dysfunction and/or tracheostomy. In this study, LIC and ACPF were greater than FVC and CPF, which meant that the Cough Aid was effective in holding the pre-cough volume and cough augmentation in patients with bulbar palsy and/or tracheostomy, because the main function of the device was to assist the compressive phase of the cough.

We assume that the Cough Aid would be particularly useful in ALS patients with bulbar palsy who have yet to be tracheostomized. In these patients, it is difficult to assist a cough by both air stacking and abdominal thrust, because they depend only on bulbar-innervated muscle function (9). Therefore, if we can substitute the glottis function of these patients, it is possible to augment enough coughing for airway secretion by manually assisted coughing. For these reasons, the Cough Aid is a suitable device, and we conclude that the use of this device could help these patients to ease respiratory secretion care, decrease pulmonary complications, and reduce the length of time for which they need to be tracheostomized. In this study, the device was more effective in increasing ACPF in the ALS group without tracheostomy than in the tracheostomy group.

In some patients with neuromuscular diseases, respiratory function worsens as muscle weakness progresses. Pulmonary compliance is lost because the ability to expand the lungs to the predicted inspiratory capacity is lost as the vital capacity decreases (18). To prevent chest-wall contractures and lung restriction, regular range-of-motion is required, which can be achieved only by providing deep insufflations, air stacking, or nocturnal non-invasive ventilation (19, 20). However, these methods are not available in patients with bulbar palsy, because it is impossible for them to hold enough air to prevent or eliminate atelectasis. The Cough Aid has an insufflation port to connect a manual insufflation bag, which can be useful to maintain lung range-of-motion and pulmonary compliance when combined with LIC. To maintain pulmonary compliance, lung growth, and the chest-wall, mobility is an important management principle in patients with restrictive pulmonary impairment. The Cough Aid is cheap, light-weight, simple, easy to operate, and does not require electricity, so it can easily be used for airway clearance in patients with bulbar palsy. We have shown that LIC with the Cough Aid was greater than VC without the device. Further studies of pulmonary compliance with the device are required.

The limitations of this study include the small number of patients and the heterogeneity of the patients. We divided the subjects into two groups, according to whether they had a tracheostomy. However, the tracheostomy group (Group 2) included patients with different diagnoses, and some patients

might have had intact glottis function, whereas others may not. Further analysis of the effects of various glottis conditions is warranted.

In conclusion, the Cough Aid is an effective device to increase cough flow and assist with air-stacking exercises by substituting the function of the glottis in patients with glottis dysfunction and/or tracheostomy. The device is small, lightweight, and easy to handle; thus it can be used in patients who cannot cough effectively with the help of existing cough-assistance methods.

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